

TETRACAINE HYDROCHLORIDE- tetracaine hydrochloride solution

NuCare Pharmaceuticals, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Tetracaine Hydrochloride Ophthalmic Solution 0.5% STERI-UNIT[®] safely and effectively. See full prescribing information for Tetracaine Hydrochloride Ophthalmic Solution.

Tetracaine Hydrochloride Ophthalmic Solution 0.5%

STERI-UNIT[®], topical ophthalmic Initial U.S. Approval: 1965

INDICATIONS AND USAGE

Tetracaine Hydrochloride Ophthalmic Solution 0.5% is an ester local anesthetic indicated for procedures requiring a rapid and short-acting topical ophthalmic anesthetic. (1)

DOSAGE AND ADMINISTRATION

One drop topically in the eye(s) as needed. Discard unused portion. (2.1)

DOSAGE FORMS AND STRENGTHS

Sterile ophthalmic solution containing 0.5% tetracaine hydrochloride (3)

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

- Do not use intracamerally since use may damage corneal endothelial cells (5.1)
- Prolonged use or abuse may lead to corneal epithelial toxicity and may manifest as epithelial defects which may progress to permanent corneal damage. (5.2)
- Patients should not touch the eye for at least 10-20 minutes after using anesthetic as accidental injuries can occur due to insensitivity of the eye. (5.3)

ADVERSE REACTIONS

Ocular adverse events: stinging, burning, conjunctival redness (6)

To report SUSPECTED ADVERSE REACTIONS, contact Alcon Laboratories, Inc., at 1-800-757-9195 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Topical Administration

2.2 Sterile Field Administration

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS SECTION

5 WARNINGS AND PRECAUTIONS

5.1 Corneal injury with Intracameral Use

5.2 Corneal Toxicity

5.3 Corneal Injury due to Insensitivity

6 ADVERSE REACTIONS

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.3 Females and Males of Reproductive Potential

8.4 Pediatric Use

8.5 Geriatric Use

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Tetracaine Hydrochloride Ophthalmic Solution 0.5% is indicated for procedures requiring a rapid and short-acting topical ophthalmic anesthetic.

2 DOSAGE AND ADMINISTRATION

2.1 Topical Administration

One drop topically in the eye as needed. Discard unused portion.

2.2 Sterile Field Administration

Open package using standard aseptic technique. The DROP-TAINER[®] dispenser may then be allowed to fall upon a sterile surface. The entire outer surface of the DROP-TAINER[®] dispenser and its contents are sterile.

3 DOSAGE FORMS AND STRENGTHS

Sterile ophthalmic solution containing 0.5% w/v tetracaine hydrochloride equivalent to tetracaine 0.44% w/v.

4 CONTRAINDICATIONS SECTION

None.

5 WARNINGS AND PRECAUTIONS

5.1 Corneal injury with Intracameral Use

Not for injection or intraocular use. Do not use intracamerally because use of Tetracaine Hydrochloride Ophthalmic Solution 0.5% may lead to damage of the corneal endothelial cells.

5.2 Corneal Toxicity

Prolonged use or abuse may lead to corneal epithelial toxicity and may manifest as epithelial defects which may progress to permanent corneal damage.

5.3 Corneal Injury due to Insensitivity

Patients should not touch the eye for at least 10-20 minutes after using anesthetic as accidental injuries can occur due to insensitivity of the eye.

6 ADVERSE REACTIONS

The following serious ocular adverse reactions are described elsewhere in the labeling:

- Corneal injury with Intracameral Use [*See Warnings and Precautions (5.1)*]
- Corneal Toxicity [*See Warnings and Precautions (5.2)*]
- Corneal Injury due to Insensitivity [*See Warnings and Precautions (5.3)*]

The following adverse reactions have been identified following use of Tetracaine Hydrochloride Ophthalmic Solution 0.5%. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Ocular Adverse Reactions

Transient stinging, burning, and conjunctival redness, eye irritation, eye pain, ocular discomfort.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies with Tetracaine Hydrochloride Ophthalmic Solution 0.5% in pregnant women. Animal developmental and reproductive toxicity studies with tetracaine hydrochloride have not been reported in the published literature.

8.2 Lactation

Risk Summary

There are no data to assess whether Tetracaine Hydrochloride Ophthalmic Solution 0.5% is excreted in human milk or to assess its effects on milk production/excretion. The

developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Tetracaine Hydrochloride Ophthalmic Solution 0.5% and any potential adverse effects on the breastfed child from Tetracaine Hydrochloride Ophthalmic Solution 0.5% or from the underlying maternal condition.

8.3 Females and Males of Reproductive Potential

No human data on the effect of Tetracaine Hydrochloride Ophthalmic Solution 0.5% on fertility are available.

8.4 Pediatric Use

Safety in the pediatric population has been demonstrated in clinical trials. Efficacy of tetracaine hydrochloride ophthalmic solution for use in pediatric patients has been extrapolated from adequate and well controlled clinical trials in the adult population.

8.5 Geriatric Use

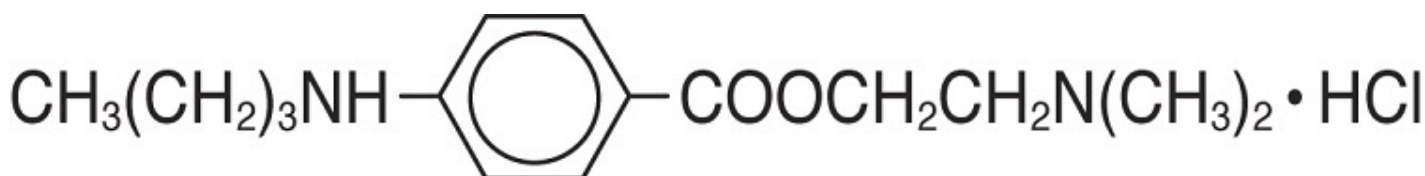
No overall differences in safety or effectiveness of tetracaine hydrochloride ophthalmic solution have been observed between elderly and younger patients.

10 OVERDOSAGE

Prolonged use of a topical ocular anesthetic including Tetracaine Hydrochloride Ophthalmic Solution 0.5% may produce permanent corneal opacification and ulceration with accompanying visual loss. Symptoms related to systemic toxicity consist mainly of effects on the neurologic and cardiovascular systems.

11 DESCRIPTION

Tetracaine hydrochloride is chemically designated as benzoic acid, 4-(butylamino)-,2-(dimethylamino) ethyl ester, monohydrochloride. Its chemical formula is $C_{15}H_{24}N_2O_2 \cdot HCl$ and it is represented by the chemical structure:



Tetracaine hydrochloride is a fine, white, crystalline, odorless powder and has a molecular weight of 300.82. Tetracaine Hydrochloride Ophthalmic Solution 0.5% has a pH of 3.7 to 5.5.

Active ingredient: tetracaine hydrochloride 0.5% w/v (equivalent to 0.44% w/v tetracaine)

Inactive ingredients: sodium chloride, sodium acetate trihydrate, acetic acid (to adjust pH approximately 4.5), Water for Injection, USP

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tetracaine blocks sodium ion channels required for the initiation and conduction of neuronal impulses thereby affecting local anesthesia.

12.3 Pharmacokinetics

The systemic exposure to tetracaine following topical ocular administration of Tetracaine Hydrochloride Ophthalmic Solution 0.5% has not been studied. Tetracaine hydrochloride is metabolized by plasma pseudocholinesterases and nonspecific esterases in ocular tissues.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies to assess the genotoxicity of tetracaine hydrochloride have not been reported in the published literature. Long-term animal studies have not been conducted to evaluate the carcinogenic potential of tetracaine hydrochloride.

Animal studies to assess the effects of tetracaine hydrochloride on fertility have not been reported in the published literature.

14 CLINICAL STUDIES

Topical administration of tetracaine hydrochloride ophthalmic solution results in localized temporary anesthesia. The maximum effect is achieved within 10–20 seconds after instillation, with efficacy lasting 10–20 minutes. Duration of effect can be extended with repeated dosing. *[see Corneal toxicity (5.2) and Overdosage (10)]* .

16 HOW SUPPLIED/STORAGE AND HANDLING

Tetracaine Hydrochloride Ophthalmic Solution 0.5% STERI UNITS is supplied as single patient use 4 mL filled in 4mL natural medium or low density polyethylene plastic DROP TAINER dispensers and natural low density polyethylene tips with white polypropylene caps in a carton of 12. Each sterilized DROP TAINER dispenser is packaged in a clear PVC and Tyvek blister. This product does not contain a preservative; discard unused portion.

68071-5079-4 bottle of 4mL StorageStore at 2°C to 25°C (36°F to 77°F). Protect from light. Do not use if solution contains crystals is cloudy& or discolored.

17 PATIENT COUNSELING INFORMATION

Eye Care Precaution

Advise patients that, due to the effect of the anesthetic, their eyes will be insensitive up to 20 minutes and that care should be taken to avoid accidental injuries.

ALCON ®

a Novartis company

Distributed by:
ALCON LABORATORIES, INC.
Fort Worth, Texas 76134 USA
© 2016 Novartis

PRINCIPAL DISPLAY PANEL

 **NuCare Pharmaceuticals, Inc.**

NDC: 68071-5079-4
Tetracaine HCl 0.5%
4mL Ophth. Soln.

Tetracaine HCl 0.5%
Lot: 000000 NDC: 68071-5079-04
MFR NDC: 0065-0741-14 Exp.: 00-00
Serial# 00000000002

Tetracaine HCl 0.5%
Lot: 000000 NDC: 68071-5079-04
MFR NDC: 0065-0741-14 Exp.: 00-00
Serial# 00000000002


68071507904-4000000-000000

Manufactured by: 3 6807150794 2
Alcon Laboratories, Inc. Fort Worth, TX 76134
Package By:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

Patent Instructions:
Place _____ drop(s) into the affected eye(s) every _____ hours.


68071507904-4000000-000000

See manufacturer's label for full list of ingredients.

Product #: R0373004
Rx Only


GTIN 00368071507942
Serial# 00000000002
Exp. Date 00-00
LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

TETRACAINE HYDROCHLORIDE

tetracaine hydrochloride solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68071-5079(NDC:0065-0741)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRACAINE HYDROCHLORIDE (UNII: 5NF5D4OPCI) (TETRACAINE - UNII:0619F35CGV)	TETRACAINE HYDROCHLORIDE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
ACETIC ACID (UNII: Q40Q9N063P)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-5079-4	4 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/09/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208135	10/26/2016	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)**Establishment**

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-5079)

Revised: 2/2021

NuCare Pharmaceuticals,Inc.